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Published in:
Revue Européenne de Droit de la Consommation = European Consumer Law Journal = Revista Europea de Derecho del Consumo

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

Push or Pull? – Information to Patients and European Law

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Summary

European Union law prohibits direct-to-consumer advertising of medicinal products for human use that are subject to prescription. However, EU law does not clarify the borderline between advertising and provision of non-promotional information on medicines, the latter being not as yet regulated at EU level. This article examines the initiative launched by the European Commission in 2008 to establish a Community legal framework on direct-to-consumer information on prescription medicines by the pharmaceutical industry. On the background of earlier attempts at reform and the growing body of case law of the European Court of Justice the article discusses whether the Commission proposal is likely to promote patient empowerment and prevent information from being used to persuade as opposed to empower patients.

Introduction

European Union law currently prohibits direct-to-consumer advertising of medicinal products subject to prescription. Article 88(1) of Directive 2001/83/EC [2] – the so-called Community code relating to medicinal products for human use – imposes

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[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as amended. *OJ* L 311, 28 November 2004, pp. 67-128.

an absolute ban on advertising of prescription products to the general public including "any form of door-to-door information, canvassing activity, or inducement designed to promote the prescription, supply, sale or consumption of medicinal products." [3] This article has been deemed by the European Court of Justice (hereafter ECJ) to amount to a complete harmonisation – in other words, Member States cannot diverge from these prohibitions in any way in their national legislation implementing Directive 2001/83/EC. Although the Directive defines the concept of advertising, albeit vaguely, it does not regulate the provision of non-promotional information on medicines. The borderline between advertising and provision of non-promotional information remains unclear. As a result Member States pursue divergent approaches to the regulation of information provision. This results in significant disparities across what ought to be a single market for pharmaceuticals, as well as cross-country inequalities in access to information and potential risks for patients, given that information of various quality can cross both EU and external borders via the media and internet.

Revision of the absolute ban on advertising has been repeatedly on the EU political agenda in the context of the debate on access to information for patients and the role of the pharmaceutical industry in providing information directly to consumers. [4] As this article will explore, there are various and indeed conflicting interests driving the debate on the relaxation of the absolute ban on advertising prescription products to patients. On the one hand, the research-based pharmaceutical industry has been pushing for a re-consideration of the absolute ban in order to ensure that it can better inform patients about the benefits and risks of their products. On the other hand, with the growth of patient activism and the desire for greater patient participation and empowerment, demands for access to information, especially information via the internet, have become more pronounced. There are obvious tensions between the provision of information to patients and persuasion driven information campaigns. The Commission's response has been to table a legislative proposal [5] in the form of a Directive amending Article 88A of Directive 2001/83/EC and a Regulation amending

3 Article 86(1) of Directive 2001/83/EC as amended, *op. cit., supra* note 2.

4 R. BAETEN, "EU pharmaceutical policies : direct-to-consumer advertising", *Social developments in the European Union,* 2009, pp. 173-200.

5 Commission of the European Communities, Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM (2008) 663 final, Brussels, 10 December 2008; Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, COM (2008) 662 final, Brussels, 10 December 2008.

Article 20 of Regulation (EC) No 726/2004. [6] The proposal intends to meet the legitimate claims of patients to have improved access to objective information and at the same time give the manufacturers of products a clearer legal framework within which to provide that information. As we shall explore in this article, the European courts have been required to consider the scope of Article 88A in a number of recent cases, but the resulting rulings do little to clarify the dividing line between non-promotional information and advertising. Does this depend on the person providing the information, or his or her objective, or both? It is doubtful if this problem can be adequately addressed on a case by case basis. Although the essential aim of Directive 2001/83/EC is to safeguard public health and prevent excessive and ill-considered advertising on medicinal products to the general public, a court judge must also weigh the competing interests at stake : safeguarding of public health against freedom of speech (including commercial speech) and the right of the general public to be properly informed, in accordance with the well-established European principle of proportionality. This is a complex exercise and there can be no guarantee that judges in 27 Member States are able to reach similar verdicts. Clearly then, a legislative initiative is required, but is the proposed legislation likely to realise its desired objectives, and will it strike the right balance between the interests of the patients, health providers, public and private health insurers, and of course the pharmaceutical industry?

In the first part of the article, we examine the background to the proposal adopted by the European Commission in 2008 and consider earlier attempts at reform and the reasons for their failure. We then set out the Commission's proposal of 2008 in more detail. The following section discusses the relevant case law of the ECJ and explains why the results of this case law are not entirely satisfactory. This section also provides an important benchmark against which to assess the proposed amendments put forward by the European Parliament at its first reading of the proposal in November 2010. In the second part of the article, we consider whether the proposed directive can serve the patient's interests, and we draw on research evidence on consumer/patient's needs and expectations to discuss whether the approach foreseen by the Directive is the right method to promote patient empowerment. The subsequent sections examine the proposal in the light of the pros and cons of shifting towards the 'pull principle', the provision of customized information directly to consumers on the benefits and risks of specific products, the provision of comparative information and the potential impact of access to non-promotional information on consumer choice in relation to their medication.

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6 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, *OJ* L 136, 30 April 2004.

I. – The European Commission proposal in the light of current EU law

A. – BACKGROUND

Advertising of prescription drugs has been banned under European directives since the adoption of Council Directive 92/28/EEC on the advertising of medicinal products for human use. [7] Although most countries ban advertising of prescription products to the general public, the USA and New Zealand have taken a less restrictive approach. In 1997 the US Food and Drug Administration (FDA) issued new guidelines that considerably relaxed its regulation of broadcast advertising of prescription products. [8] At around this period Australia, Canada and South Africa also considered relaxing their respective bans on advertising but eventually dropped these proposals. The necessity of the advertising ban and the need to enhance patient empowerment surfaced on the European policy agenda in the late 1990s. Interestingly, the debate was conducted in two separate fora. In the first place, the European Commission set up a high-level, informal process to consider the future of Europe's pharmaceutical industry and its regulation. In the second place, a regular assessment of European legislation governing the authorisation and marketing of medicinal products was conducted by the Commission with the aim to draw up a report on recommended reforms. These two processes seem to have run on parallel tracks and involve different sets of stakeholders, contributing to distrust among stakeholders as to the purported aims and objectives of subsequent reform proposals. [9]

In November 2001 the Commission put forward a legislative proposal to relax the absolute ban on advertisement of prescription drugs for a five years test period. It proposed to amend Directive 2001/83/EC in order to create a possibility for the pharmaceutical industry to inform consumers directly about their medicinal products for three types of conditions, namely, HIV/AIDS, asthma and chronic broncopulmonary disorders, and diabetes. [10] The Commission argued that a prudent lift of the ban was needed in order to meet the expectation of patient groups and make available to con-

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7 See Article 3(1) of Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use, *OJ* L 113, 30 April 1992, pp. 0013-0018. Directive 92/28/EEC was repealed by Directive 2001/83/EC (see *supra* note 2 for reference).

8 ANON, "FDA proposes new guidance on direct-to-consumer ads", *Scrip* 2258, 12, 1997.

9 See also R. BAETEN, "EU pharmaceutical policies : direct-to-consumer advertising", *op. cit., supra* note 4.

10 Commission of the European Communities, Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM (2001) 404 final, *OJ* C 75E/216, 26 March 2002, pp. 216-233.

sumers certain information under strict conditions and control. [11] The Commission included this proposal in a package of reforms to the Community marketing authorisation regime that were considered to be necessary as a result of the compulsory six-year review of the workings of that regime.

The proposal was objected to by several stakeholders including representatives of social insurance organizations, consumer organizations, health care professionals who feared that the partial lift of the ban would result in full-scale direct-to-consumer advertising for prescription medicines with harmful public health and budgetary consequences. [12] Furthermore the proposal was criticised for failing to justify the necessity of the envisaged relaxation of the ban on advertising, [13] failing to provide clear distinctions between information provision and persuasion and in particular for failing to guarantee good information practices. The proposal was in turn heavily criticized in the European Parliament and the Council and eventually rejected by both with an overwhelming majority.

Nevertheless, the European Parliament asked the Commission in 2002 to develop a consumer information strategy with the aim to ensure access of the general public to good quality, objective, reliable and non-promotional information. Consequently, Article 88 of Directive 2001/83/EC was amended by introducing an obligation for the Commission to present within three years to the European Parliament and the Council a "report on current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients". That report was due by 2007 and the Commission launched a broad public consultation process in the same year.

In the meantime the European Commission set up a High Level Pharmaceutical Forum in 2005 as a follow-up to the so-called G10 Medicines process, a high level policy forum set up by the then Commissioner for Enterprise in 2001 to examine ways to make Europe's pharmaceutical sector more competitive while at the same time optimising public health. [14] This Forum was intended to provide the political mandate for

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[11] See Article 54(2) of the Commission proposal, *op. cit.*, *supra* note 8. See also : Pharmaceutical Committee and Veterinary Pharmaceutical Committee, "Information on the outcome of the 2nd special meeting on the Review, 5 July 2001". Available at : http://ec.europa.eu/health/files/pharmacos/docs/doc2001/july/pharm_05072001_en.pdf.

[12] Health Action International Europe, "Providing prescription medicine information to consumers : Is there a role for direct-to-consumer promotion?", Symposium Report, (Brussels, Health Action International Europe, 2002).

[13] See for example, the presentation of C. MEDAWAR, "The politics of direct-to-consumer promotion of prescription medicines", in Health Action International Europe, "Providing prescription medicine information to consumers : Is there a role for direct-to-consumer promotion?", *op. cit.*, *supra* note 12, pp. 7-11.

[14] The High Level Pharmaceutical Forum brought together Ministers of EU Member States, members of the European Parliament, representatives of the pharmaceutical industry, consumer and patient organizations, insurance institutions, and health professionals. See for details, http://ec.europa.eu/pharmaforum/.

further reform as well as a broader platform for discussion on industry competitiveness and public health issues. The Forum set up working groups (WG) which considered three sets of issues – pharmaceutical pricing, therapeutic effectiveness and information to patients. The fact that several stakeholders distanced themselves from the report produced in this latter WG indicates the controversial nature of the discussions and proposals. The majority of the members of the WG agreed upon core quality principles as well as a toolbox of good practice to help patients evaluate information. The Forum then published its final conclusions and recommendations in 2008, including a set of core quality principles for patient information and a methodology for use. [15]

The Commission's first public consultation of 2007 on current practices with regard to information provision to patients on medicinal products proceeded in parallel to the work of the High Level Pharmaceutical Forum. The Commission concluded in its final report that rules and practices differed widely across Member States, with some countries applying very restrictive rules to information and relying largely on regulatory authorities, while others allowing for an increased role for the industry. [16] The report argued that such cross-country differences resulted in unequal access for consumers to information on one hand and legal uncertainties for the industry concerning cross-border activities on other hand.

Based on this report the Commission launched a second public consultation in 2008 on a summarised legislative proposal on access to information on prescription medicines. The Commission indicated that although the ban on direct consumer advertising would be maintained, a framework should be introduced to ensure patient access to objective, non-promotional information, about the benefits and risks of medicines. This would in turn require the introduction of measures to ensure a clear distinction between promotional and non-promotional information and on the roles of different players in providing that information. The Commission proposed to place continued emphasis on 'co-regulation' – that is, the involvement of public authorities and a mix of stakeholders including health care professionals, patient organisations and the industry. These co-regulatory bodies would be responsible for adopting a code of conduct on information to patients and monitoring and following up all information activities by the industry.

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[15] High Level Pharmaceutical Forum 2005 – 2008, Final report and reference documents, 2008. Available at : http://ec.europa.eu/pharmaforum/docs/ev_20081002_frep_en.pdf (last accessed May 15, 2011).

[16] European Commission, *Draft report on current practice with regard to provision of information to patients on medicinal products in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use*, (Brussels, European Commission, 2007).

B. – THE 2008 COMMISSION PROPOSAL : AMENDING DIRECTIVE 2001/83/EC REGARDING INFORMATION PROVISION BY THE INDUSTRY TO THE GENERAL PUBLIC

Further to the 2008 public consultation the European Commission adopted a proposal to amend Directive 2001/83/EC and Regulation (EC) No 726/2004. [17] Arguing that the pharmaceutical industry may be a valuable source of non-promotional information on prescription medicines, the Commission proposed to increase the role of the industry in direct-to-consumer information on its products. To increase legal clarity, it proposed to harmonize the rules on provision of non-promotional information by the industry. Harmonization in this field was expected to promote patients' access to high-quality information on a more equal basis, which is currently impeded by the wide divergence of national rules and practices. To ensure that adequate safeguards are in place, the Commission defined the type of information that may be disseminated by the industry, and set forth quality standards defined at Community level, to be applied consistently to the information content and presentation. It restricted the dissemination channels to be used by the industry to internet websites, health-related publications as defined by the national competent authorities, and written answers to information requests received from consumers. It prohibited dissemination by TV, web-TV, radio, and distribution of unsolicited materials to the public. Furthermore, it established an obligation for Member States to put in place effective monitoring mechanisms with specific rules for internet-based dissemination of information. It envisaged clarifying the distinction between advertising and non-promotional information on prescription products while maintaining the ban on advertising for all classes of prescription products.

The Commission proposal includes a number of important amendments concerning the content and dissemination of information on prescription products to the general public. First, it extends the types of information that may be disseminated by the industry. Table 1 compares the changes proposed by the Commission to the rules currently in force as set forth in Directive 2001/83/EC. It is noteworthy that pharmaceutical companies would be allowed to disseminate to the public information on non-interventional studies, [18] and present the package leaflet, the summary of product characteristics and the public assessment reports in a different way that is more under-

[17] *Op. cit.*, *supra* note 5.

[18] Non-interventional studies do not involve any clinical trial, only observation of associations between treatments experiences by subjects and their health status, and/or studies using data previously collected.

standable to patients and consumers. The industry would also be allowed to place product information in the context of the health condition to be treated.

Table 1: Type of information disseminated by pharmaceutical companies to the public

Current rules (Directive 2001/83)	*Commission proposal adopted in 2008*
Labelling, package leaflets	Labelling, package leaflets, summary of product characteristics, public assessment reports and all these presented in a way understandable by patients
Information on human health or disease BUT no reference to medicinal products	Information placing the medicinal product in the context of the illness (subject to control by competent authorities prior to dissemination)
Vaccination campaigns conducted by the industry and approved by the competent authorities	Vaccination campaigns and other campaigns in the interest of public health conducted by the industry and approved by the competent authorities
Factual announcements and reference materials (pack changes, adverse reaction warnings, trade catalogues, prices) – BUT no product claims	Factual announcements and reference materials as set forth in Directive 2001/83/EC and including information on the environmental impact of the product
	Information on non-interventional scientific studies (subject to control by competent authorities prior to dissemination)
	Information on accompanying measures to prevention and medical treatment (subject to control by competent authorities prior to dissemination)
	Prohibition of comparisons between medicinal products

Second, the proposal establishes a set of harmonized quality standards imposed on information content and presentation. These standards are meant to ensure the high-quality and non-promotional character of information provided by the industry. According to the proposed article 100d, the information should be objective and unbiased, stating both the benefits and risks of the medicinal product concerned. It must be evidence-based, verifiable, up-to-date, reliable, factually correct, not misleading, and understandable. It must take into account patients' needs and expectations, and include a statement on the level of evidence, the information source, authors, and references to underlying documentation. It should not contradict the information already approved by the competent authorities, such as the summary of product characteris-

tics, labelling and package leaflet. It should state that the medicinal product concerned is prescription-based and the information is disseminated by the industry as a means to support, not replace, the patient-doctor relationship. The information should contain an address (mail or email) allowing consumers/ patients to contact the pharmaceutical company with comments. Furthermore, companies shall make the information accessible to persons with disabilities. [19]

Third, the proposal establishes an obligation for Member States to ensure adequate and effective monitoring of information dissemination by the industry. The proposed article 100h places responsibility on Member States' national competent authorities to control such information *prior to dissemination*, unless its content is already approved by the competent authorities (national or European), or an equivalent level of monitoring is ensured through a different mechanism. In case of medicinal products authorized under Title II of Regulation (EC) No 726/2004 certain types of information would be subject to vetting by the European Medicines Agency [20] *prior to dissemination*. This includes information about non-interventional scientific studies, information about accompanying measures to prevention and treatment, and product information set in the context of the health condition to be treated or prevented. The proposal to amend Regulation (EC) No 726/2004 creates a responsibility for the European Medicines Agency to deliver opinions on such types of information prior to dissemination. Consequently, the Agency would be empowered to object to the information submitted to it by the pharmaceutical company in case of non-compliance with the proposed Directive.

The proposal allows for control by self-regulatory or co-regulatory bodies on a voluntary basis. The Commission would be responsible to draw up (in consultation with Member States) and update regularly a code of conduct for the industry with guidelines concerning information provision. Furthermore, the proposal sets forth specific monitoring rules for information dissemination via the internet. Accordingly, pharmaceutical companies would be required to register with the national competent authority the websites containing information on prescription medicines. Registration of such sites must be made prior to making them available to the public. Safeguards proposed include prohibition of identification of consumers who access these websites, as well as prohibition of active distribution of unsolicited material to the public, web-TV and links to other, non-registered sites. Reproducing registered websites on other sites

[19] See article 100f(1) of the Commission proposal, *op. cit.*, *supra* note 7.

[20] The European Medicines Agency is responsible for the scientific evaluation of medicinal products applying for Community marketing authorization. See Regulation (EC) No 726/2004, *op. cit.*, *supra* note 6.

would only be allowed in case of identical content. The Member State where the website is registered would be responsible for content monitoring.

The proposal includes specific monitoring rules for cross-border activities with the aim to remove undue impediments to information flow within the internal market. Accordingly, a Member State would not be allowed to adopt any measure with regard to the content of a website registered with the competent authority of another Member State unless it has reasons to doubt the quality of the translation and/ or compliance of the information disseminated with the quality standards. In case of doubt the Member State concerned could ask the pharmaceutical company for a certified translation of the website and/ or inform the Member State of registration about its doubts. The Member States concerned would have two months at disposal to reach an agreement or else, refer the case to the Pharmaceutical Committee of the Commission.

Fourth, Member States would also be responsible for ensuring – under an accelerated procedure – adequate and effective sanctions for non-compliance with the rules set forth in the proposal. In particular, States would be responsible for establishing the obligation to sanction non-compliance, determining the penalties for infringement, and conferring on courts or administrative authorities the power to order the cessation and/or prohibition of dissemination of non-complying information. The proposal makes it clear that it would be the responsibility of Member States to ensure that pharmaceutical companies keep and make available for monitoring a sample of all information disseminated including also data on volume, recipient, dissemination method and date. States should also ensure that pharmaceutical companies comply with decisions taken by authorities.

It is evident that the proposal is the result of a delicate balancing act in which the Commission has tried to reconcile competing interests. Before turning to the reception of the proposal by the European Parliament at its first reading, it is necessary to consider the relevant case law of the ECJ of Directive 2001/83/EC on advertising and information.

C. – Case law developments

The European courts have been asked on a number of occasions to rule on the scope of Article 88 and a number of related provisions in Title VIII, and to determine whether the Directive's prohibitions on advertising extend to various forms of promotional activities, including financial incentives by persons or bodies not associated with commercial interests. This case law exposes the weakness of the current definitions and it reveals that faced with borderline cases, the ECJ has erred on the side of caution, and taken a strict approach to the reach of the prohibition on advertising. In so far as estab-

lishing a 'bright line' between persuasion and information remains necessary, the results of that case law are not entirely satisfactory.

1. – *Complete Harmonisation and Directive 2001/83/EC*

On 8 November 2007 the ECJ handed down a landmark judgment on the interpretation of Directive 2001/83/EC : *Gintec International Import-Export GmbH v Verband Sozialer Wettbewerb eV.* [21] Until then, one of the most controversial questions in connection with advertising medicinal products in many Member States including Germany had been whether the strict provisions of national law – and in Germany, the Remedies Advertising Act (*Heilmittelwerbegesetz – HWG*) were in line with the Community code.

The ECJ clearly stated that "... *Directive 2001/83 brought about complete harmonisation in the field of advertising of medicinal products and lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that directive.*" Where the directive does not expressly allow the Member States to deviate from its standards, they may not provide for stricter rules.

The ECJ found that the restrictions of the HWG went beyond the standards of the Community code in various respects. In particular, the ECJ held that the Community code did not prohibit the use of third party statements in such a general and unconditional way as the relevant provision of the HWG, but only under certain conditions, *i.e.* if the advertising "refers, in improper, alarming or misleading terms, to claims of recovery."

However, in the case at hand, the evaluation of the "consumer survey" published by Gintec for advertising purposes showed that a significant part of the consumers had decided to use the ginseng preparation on a long-term basis, and two thirds of those questioned were reported to use the product for the purpose of reinforcing their well-being. In this respect, the ECJ recalled that the Community code "*requires the Member States to provide, in their national legislation, for a prohibition on the use, in the advertising of medicinal products to the general public, of statements from third parties where they give the impression that the use of the medicinal product contributes to the reinforcement of general well-being.*"

Even if the Court concluded that the Directive provided for a complete harmonization on the rules relating to advertising, the Court was not required to deal with the definition of advertising as such and the relationship between the absolute ban on advertising and on information provision or other forms of promoting medicines.

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[21] ECJ, *Gintec International Import-Export GmbH* v. *Verband Sozialer Wettbewerb eV.* (case C-374/05), *ECR* (2007), I-09517.

2. – *The* Damgaard *Case*[22]

This issue was however squarely before the Court in *Damgaard*. This case originated from a Danish court and involved the legality of information on a particular treatment for gout that was available in Sweden, but not in Denmark. Mr. Damgaard is a journalist against whom criminal proceedings were initiated in Denmark because of an alleged violation of the ban on advertising for an unauthorised medicinal product in Denmark. Mr. Damgaard argued that he was an independent journalist who did not have any financial interest in the company that produces the product and that his communication on the product did not constitute "advertising."

The ECJ considered that the definition of "advertising" in Directive 2001/83/EC emphasizes the purpose of the message, *i.e.* the promotion of the prescription, supply, sale or consumption of medicinal products. Such information however does not need to be disseminated in the context of commercial activity in order to be considered advertising. The ECJ ruled that the dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising, even though the third party is acting on his own initiative and is completely independent from the manufacturer or the seller of the medicinal product.

In Damgaard, therefore, the ECJ gave "advertising" a broad meaning in light of the essential aim of the Community Medicinal Code to safeguard public health : "*... the wording of Directive 2001/83/EC does not rule out the possibility that a message originating from an independent third party may constitute advertising. Nor does the directive require a message to be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising. In that regard, it must be stated that, even where it is carried out by an independent third party outside any commercial or industrial activity, advertising of medicinal products is liable to harm public health ...*"

Therefore, for the purposes of the Directive, "advertising" appears to include any communication regarding medicinal products that may be liable to harm public health.

3. – *The* ABPI *Case*[23]

In the ABPI case the Court was asked to rule on the scope of article 86(1) and article 94(1) of Directive 2001/83/EC. Doctors and other health care professionals are granted specific powers to write prescriptions and if they issue prescriptions fund-

22 ECJ, *Damgaard* (case C-421/07), *ECR* (2009), I-02629.

23 ECJ, *Association of the British Pharmaceutical Industry* v. *Medicines and Healthcare Products Regulatory Agency* (case C-62/09), *ECR* (2010), judgment of 22 April 2010.

ed by the National Health Service (NHS) they must comply with NHS rules and prescription controls. As part of an overall national policy to reduce costs the bodies responsible for providing medical services – Primary Trusts (PMT) and Local Health Boards (LHB) – introduced schemes aimed at medical practices inducing them with financial incentives to prescribe to their patients either specific named medicinal products or generic medicine products. The PMTs and LHBs drew up categories of products based on therapeutic equivalence and then provided for financial inducements based on prescribing targets which in turn would reduce the PCT's expenditure by favouring the cheapest production within the appropriate therapeutic class.

The ABPI, the industry association objected to this scheme and complained to the national authorities responsible for its overall implementation. Having failed to persuade these authorities to abandon the policy, the ABPI challenged the system on the grounds that it infringed Article 94(1) of the Directive which prohibits financial inducements to doctors to change their prescribing behaviour. The English High Court sought clarification from the ECJ on the question of whether Article 94(1) could indeed be interpreted to prohibit a public scheme designed to offer inducements to doctors to prescribe a specific product, even if the aim of the scheme is to reduce overall expenditure on medicines. The European Commission intervened in the case to support the ABPI and to recommend to the ECJ that it should indeed interpret Article 94(1) accordingly. The UK government, supported by the Czech, Estonian, Spanish, French and Dutch governments argued that Article 94 only applied to commercial inducements offered by commercial as opposed to public bodies. Essentially then the question before the Court was similar to that before it in the *Damgaard* case, what is the scope *ratione personae* of Articles 86 and 94 of the Directive? The Court in that case had stressed the purpose of the activity, and not the person called upon to carry it out.

In the ABPI case the Advocate General (AG) in his opinion of 11 February 2010, followed a similar approach to the interpretation of Article 94 – the purpose of Article 94 being to preserve the independence and objectivity of a doctor's prescribing decision and to protect the integrity of the relationship between patient and doctor. The AG was especially concerned that if Article 94 was found to apply to commercial interests, but not to public interests this would undermine its purpose, because it would mean that a wide category of persons outside the pharmaceutical industry could influence doctors prescribing by means of financial inducements. These might include health provision and health service providers, charities or other non-profit entities such as patient interest groups. If a different set of rules applied to such groups this would be contrary to the aim of the Directive, which is to maintain objectivity and independence in prescribing. Having concluded that the Article also applied to public authorities, the AG then went on to consider if the measure amounted to promotion of

a medicinal product. Relying on the Damgaard case that the definition emphasises the purpose of the message and not its provider, the AG considered that the UK scheme amounted to a form of promotion and was therefore also prohibited.

The ECJ did not however follow this line of reasoning. The Court ruled within two months on the issue, on 22 April 2010, and held that its approach in Damgaard could not be applied in a case where public authorities need to disseminate information about a medicinal product. Similarly as regards financial inducements, the Court held that although the prohibition may apply to independent third parties who are not acting for commercial purposes or for non-profit purposes, the prohibition cannot apply to national public health authorities, which are responsible for ensuring the very rules for which that directive forms part, and for defining priorities for addition in relation to public health policy, in particular in so far as this concerns the rationalisation of public expenditure. As health policy defined by a Member State does not pursue any commercial aim, a financial incentive that forms part of such a policy cannot be regarded as commercial promotion.

It is submitted that the ECJ's reasoning is not entirely convincing. First, the ECJ's ruling is predicated on a distinction between commercial interests, which would engage Article 94(1) of Directive 2001/83/EC, and non-commercial, political matters, which would not. This is inconsistent with *Damgaard*, which – although in relation to Article 86(1) – appeared to collapse the distinction between commercial and non-commercial motivations. The ECJ pointed out that, in general terms, health policy and spending do not pursue any profit-making or commercial aim. Yet those GPs who prescribe the medicinal products favoured by the prescription incentive schemes enjoy larger profits than those who do not. This blurs the distinction between commercial and non-commercial objectives, and the ECJ's emphasis on the supposed non-commercial character of prescription incentive schemes appears misplaced.

EU law does not express any preference one way or the other in relation to the organization of Member States' healthcare systems, provided Member States do not construct barriers to the free movement of goods or encourage distortions of competition. The result is that national public health authorities can offer incentives to GPs and other appropriate practitioners to favour the prescription of specific medicinal products over others because there is no prohibition on such a practice in EU internal market law.

As the formation and implementation of health policy necessarily involves financial considerations, public health authorities and fiscal policy are indissolubly linked. The ECJ's reliance on the commercial/non-commercial dichotomy, it can be argued, does not fit easily with the confluence of health and economic policy. Prescription incentive schemes sponsored by public health authorities cannot be interpreted in isolation as

commercially driven, economic phenomena but are an integral part of health policy. Finally, the ECJ's reasoning that the same risk of harm to public health that *Damgaard* entailed could not apply in the ABPI case is misconceived. Prescription incentive schemes may also carry a risk of harm to public health. As the ECJ recognized, switching drug therapies to comply with prescription incentive schemes "*might, in certain cases ... have adverse consequences for the patient.*"

Two further cases decided on 5 May 2011 by the Court throw further light on the distinction between advertising and information provision.

4. – *Information to healthcare professionals* – *Case* Novo Nordisk AS v. Ravimiamet [24]

In his opinion delivered on 19 October 2010, the Advocate General (AG) had considered that the inclusion of some information in advertising material, addressed to doctors, which are compatible with the Summary of Product Characteristics (the SmPC) but are not part of it, may comply with Directive 2001/83/EC. An advertisement for an insulin product, inserted in an Estonian medical review by Novo Nordisk, stressed that in practice, a once-a-day injection applies to 82% of the patients and that weight loss could not be excluded. As both the percentage and the possible weight loss were not included in the SmPC, the Estonian Office for Medicinal Products required the termination of the advertisement.

This decision was challenged by Novo Nordisk before the competent Estonian Court on the grounds that the additional information included in the advertisement was lawful and was quoted from scientific and medical literature. The issue was referred to the ECJ for an interpretation of Article 87(2) of Directive 2001/83, which states that "*all parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.*"

Hence the main issue for the Court was to clarify whether advertising can provide information which is compatible with, but not included in the SmPC, and if so, to what extent. According to the Court the primacy of public health protection over the freedom of speech as well as the principle of proportionality cannot justify to limit the prohibition only to advertising claims which contravene the SmPC. In principle, quotations from new scientific results which go beyond the information included in the SmPC should be prohibited in advertising to both the public and to qualified health professionals as the marketing authorization holder is under the obligation to regularly update its SmPC. However, the Court followed the AG's Opinion and ruled that the prohibition on advertising extends to adverts for medicinal products directed at quali-

[24] ECJ, *Novo Nordisk AS* v. *Ravimiamet* (Case C-249/09), *ECR* (2011), judgment of 5 May 2011.

fied health professionals as well as the general public, but further it held that some information which should be – but is not – included in the SmPC might be included in such advertising. This could be the case of data which confirms or specifies certain information included in the SmPC, and the advertising includes a reference to a specific reduction rate based on a new scientific survey. This ruling underlines the fundamental importance for companies, to draw an appropriate distinction on a case-by-case basis between advertising and scientific information.

5. – *Information for the general public : Case* MSD v. Merckle [25]

In its *Damgaard* judgment the ECJ had left open the issue of how to draw a distinction between advertising of prescription products destined to the general public – which is of course strictly prohibited by Article 88 of Directive 2001/83 – and lawful information provided in relation to the same products. In Damgaard, the AG had suggested that the fundamental criterion lies in the objective pursued. If the deliberate and direct intention was to promote "*the prescription, supply, sale or consumption*" of medicinal products, it would constitute unlawful advertising; while purely informative material that was being disseminated without promotional intent, would not fall under European prohibition of advertising.

In *MSD* v. *Merckle*, the issue of advertising of prescription products to the general public arose once again. The AG, in her opinion issued on 24 November 2010, proposed that pharmaceutical firms should be allowed to provide the general public with information on prescription-only medicinal products, provided that they do not pursue any promotional goal, as this is the main criterion to distinguish information from advertising.

MSD was accused of breaching the ban of advertising for prescription-only products, as it had published on a non-password protected website, in its entirety, a patient information leaflet together with a photo of the product pack for three of its prescription-only medicines, namely "Vioxx", "Fosamax" and "Singulair". The German Supreme Court referred the issue to the ECJ for a preliminary ruling to clarify whether the scope of application of Article 88(1)(a) extends to advertising of prescription products to the general public, which contains "only information which was placed before the authorising authority *in the course of the marketing authorisation procedure and which is* accessible in any event to every person acquiring the product, *and where that information*

[25] ECJ, *MSD Sharp & Dohme GmbH* v. *Merckle GmbH* (Case C-316/09), *ECR* (2011), judgment of 5 May 2011.

[...] can be accessed only through the internet when the party concerned takes steps to do so?".

It is of interest to note that Denmark, intervening, has argued that an assessment of the intention of the author of the communication, taking into account the form and the content of the latter, is essential to check whether or not it must be considered as advertising. Denmark also added that the literal and integral reproduction of information on medicinal products which has been approved by the authorising authority should not be considered as advertising, provided that such information is not altered.

The Commission had taken a similar view in its observations, and recalls that (i) the definition of advertising depends on the aim sought by the author of the communication and (ii) the ban of advertising laid down by Article 88 must be proportionate to the aim pursed by the Directive, namely the protection of public health. The Commission also emphasized the choice of the channel of communication, as MSD had made the litigious information available only online via a "pull service", meaning that the Internet user had to search for the piece of information, unlike "pop-ups", which could be categorized as 'push' type information or persuasion.

According to the AG's Opinion, the answer lies in the delicate distinction between advertising – that the Directive vaguely defines – and information – which is not as yet regulated by the Directive. The AG proposed in order to distinguish the two concepts, to focus on the intention of the author of the litigious communication, while taking into account the identity of the author, the object, the content, the technical features of the communication and the target audience. The purpose of this set of criteria – close to these proposed by the Commission and by the AG in the *Damgaard* case – is to help the national judge determine whether or not the author seeks to promote products which are featured in the communication. Hence the AG claimed that the definition of advertising should be strictly interpreted. She argued that the fact that a pharmaceutical company makes information on its products available to the public does not *ipso facto* imply an intention of promotion. Furthermore, Article 88 does not prohibit every kind of communication on prescription medicinal products. Information that has been previously approved by competent authorities could not be banned for the sole reason that it is related to prescription-only medicines. [26]

The AG therefore concluded that Article 88 of Directive 2001/83/EC does not prohibit communication to the general public on prescription medicinal products, as long as it contains only information which was submitted to the authorising authority,

[26] The AG adds that if this information is altered, the opposite interpretation could perhaps then prevail, as the published information is not related to safety. Further, in order to prevent self-medication, the AG proposes that pharmaceutical companies include a warning recalling that published information does not equal to consultation.

which is accessible in any event to every person acquiring the product, and which can be accessed only through the internet when the party concerned takes steps to do so. The ECJ has now followed this Opinion and has ruled that the dissemination of information of prescription products on the manufacturer's website which consists solely of the faithful reproduction of the packaging and a literal reproduction of the SmPC and is not accompanied by any additional elements is not dissemination for advertising purposes (see para 43). The information in question was only available according to the 'pull' system. If the information had been rewritten or edited, this would however have been classified as advertising, and as such, prohibited.

D. – The European Parliament Amendments

Co-incidentally, the European Parliament adopted it position on the Commission's draft legislation on 24 November 2010. These amendments essentially focus on the obligation of pharmaceutical companies to provide information to the general public, while further breaking down the content, the form and the goals of such information. The Parliament makes a distinction between information that the industry shall make available to the general public – labeling, package leaflet and assessment report approved by competent authorities during the course of marketing authorisation – and information that the industry may make available, after having been approved by the competent authorities, such as information on environmental impact, prices, pack changes, instructions for use, pre-clinical tests, clinical trials. The Parliament also emphasizes the ban of unsolicited information by changing the word "disseminate" to "make available" and adding the printed press to the list of unauthorised channels of communication. As to the quality criteria that information must fulfill in order to be made available to the public, the Parliament extends the list and highlights the patients' needs. The Parliament insists that pharmaceutical companies and any third parties related to them clearly identify themselves while making information public. Further, additional articles in the Commission's proposal are added to recall the right of any other party, such as the press and patient organizations, to express their views on prescription-only medicines. Finally, regarding monitoring and control, the Parliament proposes to involve the Commission in the implementation of the proposed Directive and the industry in the financing of the monitoring. The Commission has indicated that it will accept a majority of these amendments and incorporate them in a revised proposal, to be launched in October 2011.

It is apparent that there is a certain convergence between the approaches developed by the MSD case, the Commission and the European Parliament. However, the support of the European Council of Ministers remains pivotal to amend the current Directive. At this stage, several Member States remain reluctant to authorize the industry to

make information on prescription-only medicines available directly to the general public. In the *MSD* v. *Merckle* case, Portugal, Poland, Hungary and the Czech Republic intervened before the ECJ to argue that Article 88 prohibits any kind of communication on prescription medicinal products undertaken by pharmaceutical companies.

II. – Assessment

In this second part of the article, we will now turn to an assessment of the proposed Directive adopted by the European Commission in 2008 and discuss its potential impact. We first examine whether the proposal can in fact achieve its stated objective – to serve the patient's interest – in the light of existing research evidence on the role and impact of medicine information from the perspective of consumers.

A. – DOES THE PROPOSAL SERVE THE PATIENT'S INTEREST?

The Commission has launched the proposal under the labels of patient empowerment, informed treatment choice and rational use of medicines. The vision of the Commission proposal is the patient empowered to make the best decisions concerning his/ her medication, which is expected to enhance the rational use of prescription medicines. [27] It is therefore important to examine whether the proposal serves the interest of patients and consumers. The following part assesses the proposal in the light of research evidence on consumers' needs and expectations concerning written – printed and internet-based – medicines information and the effectiveness thereof. Furthermore, it discusses whether increasing the role of pharmaceutical companies in direct-to-consumer information is the right method to promote patient empowerment. The analysis focuses on the version proposed by the Commission and addresses the relevant amendments made by the European Parliament. It explores primarily the perspective of consumers and addresses also the perspective of other stakeholders (health professionals, insurers, regulators) where relevant.

B. – THE ROLE OF MEDICINES INFORMATION FROM THE PERSPECTIVE OF THE CONSUMER : SHIFTING TOWARDS THE PULL PRINCIPLE

Existing research evidence shows that patients and health professionals perceive the role of written medicines information differently. Based on a systematic literature

[27] It is noteworthy that the Commission proposal neither defines, nor operationalizes the concept of rational use of prescription medicines.

review Raynor *et al* conclude that health professionals consider patients' compliance with the prescribed treatment as the primary role of written medicines information. Patients, however, consider that the primary role of such information is to equip them to participate in decision-making if they choose to do so, rather than ensure compliance with orders issued by doctors. [28] This concerns both the initial decision about taking a given medicine or not, and ongoing decisions related to treatment management and interpretation of symptoms. Patients differ in terms of their desire to get involved in decision-making about their medication, and their desire to do so changes over time. Some choose to delegate decision-making entirely to the doctor. Pushing unsolicited information on such patients can be counterproductive by leading to anxiety and uncertainty. [29] Relevant research evidence supports the claim that patients should be allowed to decide whether they want to be informed and how much information they want to obtain. This is commonly known as the "pull principle" : patients should be empowered to access information if they choose to do so, but safeguarded from unsolicited information "pushed" on them.

The proposal put forward by the Commission intends to reinforce the "pull principle" by prohibiting the use of certain information channels by pharmaceutical companies, namely, TV, web-TV, radio and active distribution of unsolicited materials to consumers. These safeguards were, however, found insufficient by the European Parliament, which replaced the permission for the industry to disseminate information to consumers with the obligation to make information available to consumers. It also inserted a right for patients to access information on prescription medicines. These amendments reflect the intention of the Parliament to shift the emphasis from the right of the industry to disseminate information to the right of consumers to access information. [30] In addition, the version adopted by the Parliament prohibits the dissemination of such information via printed press arguing that patients are not protected against unsolicited information disseminated through this channel.

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[28] D.K. RAYNOR, A. BLENKINSOPP, P. KNAPP, J. GRIME, D.J. NICOLSON, K. POLLOCK, G. DORER, S. GILBODY, D. DICKINSON, A.J. MAULE and P. SPOOR, "A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines", *Health Technol Assess* 11(5), 2007.

[29] D.K. RAYNOR *et al.*, "A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines", *op. cit., supra* note 28, p. 86.

[30] See amendments 5, 28 and 35 made by the Parliament to the Commission proposal and the justification thereof.

C. – PERSONALIZED MEDICINE INFORMATION SET IN THE CONTEXT OF THE INDIVIDUAL'S HEALTH CONDITION

Research evidence shows that patients need information that enables them to find out whether a given medicine is suited to their individual health condition. [31] Patients' information needs change over time depending on individual circumstances. [32] Therefore, patients need information that is tailored to them and set in the context of their actual situation. This need is particularly relevant in case of information on benefit-risk of medicines. The outcome of a study carried out by the European Medicines Agency shows that patients want to access personalized benefit-risk information. [33] Patients define the benefit-risk balance as the improvement expected in their health condition by taking the medicine compared to the constrains (particularly adverse effects). However, the information available on the benefit-risk balance of a medicine is usually the result of assessment performed at population level, which is not necessarily a reliable predictor of the individual outcome. For example, the benefit-risk information available from regulatory authorities is usually generated by assessments conducted in larger populations and based on population-level data. [34] The Agency's report concludes that it is necessary to improve communication with patients in order to help them interpret and make use of the benefit-risk information in the context of their individual condition.

A controversial issue raised by the proposal is whether pharmaceutical companies should have a greater role in providing customized information directly to consumers on the benefits and risks of prescription medicines. The pharmaceutical industry demands a greater role in the process of risk-benefit information, both in response to individual inquiries received from consumers and more generally. [35] The industry argues that any consumer should be entitled to question a pharmaceutical company about its products and receive the information he or she seeks. The EU pharmaceutical legislation already allows the industry to provide written answers to information

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31 K. NAIR, L. DOLOVICH, A. CASSELS, J. MCCORMACK, M. LEVINE, J. GRAY, K. MANN and S. BURNS, "What patients want to know about their medications : focus group study of patient and clinician perspectives", *Can Fam Physician* (48), 2002, pp. 104-110.

32 Healthcare Commission, *National NHS patient survey*, (London, The Stationery Office, 2005).

33 European Medecines Agency, *Information on benefit-risk of medicines : patients', consumers' and healthcare professionals' expectations*, (London, European Medicines Agency, 2009).

34 It is noteworthy that the European pharmaceutical legislation defines the benefit-risk balance as an assessment of the positive therapeutic effects vs. the risks relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health (Article 1(28) of Directive 2001/83/EC as amended). This definition reflects the focus on population-level assessment, which should be distinguished from the assessment of the benefit-risk balance at the level of the individual patient.

35 J.M. SHAW, G. MYNORS and C. KELHAM, "Information for patients on medicines", *BMJ* (331), 2005, pp. 1034-1035.

requests received from the general public and accompany the correspondence with non-promotional materials. Such direct-to-consumer communication and dialogue is allowed under Article 86(2) of Directive 2001/83/EC as amended, [36] transferred in the proposed Article 100c(c). The Commission proposal ensures that consumers may send inquiries and receive replies in any of the official languages of the European Union which are official languages in the Member State where the given medicine is authorized. [37]

In principle, such possibilities could help patients to obtain information that is tailored to them. However, the proposal leaves it unclear what kind of information pharmaceutical companies can provide in response to consumers' questions and document inquiries on prescription medicines. Representatives of the industry argue that the persisting legal uncertainty makes companies reluctant to give anything but the most basic information in response to individual inquiries, which is contrary to the patient's interest. [38] More clarity is demanded also by other stakeholders, albeit a different reason. Representatives of health insurance and social protection organizations, consumer organizations and health professionals have expressed strong concerns that pharmaceutical companies might use this channel to contact consumers with promotional materials and influence them directly, bypassing health professionals. [39]

Given the controversies around consumer inquiries directed at the industry, the European Parliament has sought some clarifications concerning the type of information that pharmaceutical companies can and should provide in response to such requests. It inserted an amendment creating an obligation for companies to provide answers to information requests about medicinal products and specifying the list of printed materials that should be made available. The list includes the most recent package leaflet, summary of product characteristics, labelling, and publicly accessible version of the assessment report of the medicinal product as approved by the competent authorities. In addition, the amendment specifies the type of information that the industry *may* make available on a medicinal product upon specific requests received from consumers. This includes information on prices, pack changes, adverse reaction warnings, environmental impact, instructions for use, the pharmaceutical and pre-clinical tests

[36] Article 86(2) of Directive 2001/83/EC as amended stipulates that correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a medicinal product does not amount to advertising.

[37] Article 100e(2) of the Commission proposal.

[38] J.M. SHAW *et al.*, "Information for patients on medicines", *op. cit.*, *supra* note 35.

[39] AIM, ESIP, HAI Europe, ISDB and MiEF, "Legal proposals on 'information' to patients by pharmaceutical companies : a threat to public health", Joint briefing paper, Brussels, 2009. See also B. MINTZES, "Response to European Commission Public Consultation, Legal proposal on information to patients", 2008.

and the clinical trials that are contained in the publicly accessible version of the assessment report, and a summary of frequently submitted information requests by the general public together with the answers. Any information shall include also the contact details of the national competent authorities to enable consumers to submit comments, complaints about misleading or inappropriate information, and to report suspected adverse reactions. [40] Companies shall ensure that information is available both in electronic and printed form as well as in formats suitable for visually impaired persons whenever needed. The information shall be approved by the competent authorities (or in the case of EU marketing authorisation, by the European Medicines Agency), *prior* to its being made available. Inquiries sent by consumers and the replies of the industry shall be recorded and monitored. [41]

Pharmaceutical companies also demand a greater role in providing consumers with information that links the prescription medicine to relevant clinical information on the condition to be treated. The current EU rules on advertising restrict the possibilities of pharmaceutical companies to meet patients' need for condition-based information on prescription medicines. Article 86(2) of Directive 2001/83/EC stipulates that information relating to human health or diseases that contains a reference, direct or indirect, to medicinal products is considered advertising and is therefore prohibited in case of prescription medicines. The Commission proposal allows pharmaceutical companies to disseminate directly to consumers information that presents the prescription product "*in the context of the condition to be treated or prevented.*" [42] This could help to overcome the difficulties stemming from the current separation of prescription medicine information from information on health condition and diseases. [43] On the other hand, the Commission proposal maintains the restriction that information relating to health or diseases is exempted from the advertising prohibition if and only if no reference is made to prescription products [44]. Given this contradiction, it remains unclear what pharmaceutical companies can lawfully do to meet patients' need for condition-based information.

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40 Amendments 42 and 44.

41 Amendment 41.

42 See Article 100b(d) of the Commission proposal.

43 Such difficulties may occur for example in cases when the main indication of a medicine is not the disease for which it has been prescribed. See also D.K. RAYNOR *et al.*, "A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines", *op. cit.*, *supra* note 28, p. 28.

44 See article 1 of the Commission proposal stating that title VIII on advertising does not cover "information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products".

D. – Comparative information on prescription medicines

Informed choice is only possible if appropriate information on the available choices is accessible and allows for comparison between existing alternatives. This goes beyond finding out about the individual characteristics of a given medicine. [45] Research evidence shows that consumers want to find out how a given medicine compares to other treatment options and to the option not to treat, primarily in terms of the level of efficacy, [46] the long- and short-term side-effects, [47] as well as the treatment duration and cost. [48] It is hardly possible to empower patients to make informed treatment choices without ensuring their access to reliable comparative data on available options.

Several stakeholders have criticized the Commission proposal for its failure to address consumers' need to access comparative information on prescription medicines. Representatives of health insurance and social protection organizations, consumer organizations and health professionals argue that reliable comparative information should have been included in the Commission proposal as the prime principle. [49] It is noteworthy that the High Level Pharmaceutical Forum has addressed this issue in its recommendations to enhance access to information on disease and treatment. As mentioned before, the Forum developed a set of quality principles on information to patients and a methodology of use of these principles. The quality requirements stipulate that information materials disseminated to patients should always indicate which treatment choices exist. [50] Two members of the Pharmaceutical Forum suggested a requirement to describe all validated treatments equally well, including the benefits, harms, risks and information on prevention. [51] These recommendations were however omitted from the Commission proposal, which includes no requirement to indicate the existing treatment options. In fact, the Commission proposal prohibits pharmaceutical companies to disseminate information that includes comparisons between medicinal products. [52]

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45 Which is, by the way, the usual type of information included in the information leaflets inserted in the packaging of prescription medicines.

46 D.A. Newby, S.R. Hill, B.J. Barker, A.K. Drew and D.A. Henry, "Drug information for consumers : should it be disease or medication specific? – Results of a community survey", *Aus N Z J Public Health* (25), 2001, pp. 564-570; K. Nair *et al.*, "What patients want to know about their medications...", *op. cit.*, *supra* note 31.

47 P.S. Melnyk, Y.M. Shevchuk and A.J. Remillard, "Impact of the dial access drug information service on patient outcome", *Ann. Pharmacother* (34), 2000, pp. 585-592.

48 K. Nair *et al.*, "What patients want to know about their medications...", *op. cit.*, *supra* note 31.

49 AIM *et al.*, "Legal proposals on 'information' to patients by pharmaceutical companies...", *op. cit.*, *supra* note 39. See also B. Mintzes, *op. cit.*, *supra* note 39.

50 High Level Pharmaceutical Forum 2005-2008, *Final report and reference documents, op. cit., supra* note 15.

51 *Ibidem* note 50.

52 See Article 100d(3) of the Commission proposal.

Representatives of health insurance and social protection organizations, consumer organizations and health professionals argue that the pharmaceutical industry is not an appropriate source of comparative medicines information for consumers due to conflict of interest. [53] Such arguments emphasize that pharmaceutical manufacturers cannot be expected to disseminate information that compares their own products to those of their competitors and yet remains unbiased, reliable and non-promotional. The European Parliament, however, proposes a greater, albeit controlled role for the industry in the provision of comparative information to the public. It has inserted an amendment allowing the industry to disseminate comparative information on the quality, safety and efficiency of different medicinal products if those comparisons are included in the officially approved documents, such as the Summary of Product Characteristics. [54] It also allows the industry to disseminate comparative information included in scientific studies published by the competent national authorities or the European Medicines Agency, and/or contained in the summary of the European Public Assessment Reports. The Parliament argues that such scientific studies constitute a valuable source of information for consumers and their dissemination should be not discouraged. It remains to be seen whether pharmaceutical companies will assume a role in strengthening the validated processes to provide comparative medicine information for the benefit of consumers.

E. – EFFECTIVENESS OF INTERNET-BASED MEDICINES INFORMATION FROM THE PERSPECTIVE OF CONSUMERS

Although the proposed Directive puts special emphasis on the internet as an information channel consistent with the "pull principle", little is known about the effectiveness of internet-based, non-promotional medicines information from the perspective of the consumer. Existing research on the use of the internet for accessing information on medicines shows that consumers who rely on verbal and written medicine information are also likely to rely on the information obtained via the internet. [55] Consumers rarely try to find out the authors or owners of websites when seeking health information, and rarely check the source of the information, the disclaimers or disclosure statements, and the date of publication. [56] The few available studies conclude that

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53 AIM *et al.*, "Legal proposals on 'information' to patients by pharmaceutical companies...", *op. cit., supra* note 39.

54 Amendment 45.

55 A.M. MENON, A.D. DESHPANDE, M. PERRI, G.M. ZINKHAN, "Trust on online prescription drug information among internet users : the impact on information search behaviour after exposure to direct-to-consumer advertising", *Health Mark Quart.* (20), 2002, pp. 17-35, cited also by U. NÄRHI, *Drug information for consumers and patients – A review of the research*, (Helsinki, National Agency for Medicines, 2006).

56 G. EYSENBACH and C. KÖHLER, "How do consumers search for and appraise health information on the world wide web? – Qualitative study using focus groups, usability tests, and in-depth interviews", *BMJ* (354), 2002, pp. 573-577.

internet-based information and interactive discussion do not necessarily affect patients' disease management. [57]

The discussion around the use of the internet as a source of non-promotional medicine information has focused so far on the general characteristics of the internet. [58] Easy and speedy use, wide access not confined to state borders, the possibility of proactive search for information, the possibility to interact with the patient and adapt the information to his/her needs, anonymity and the use of multimedia tools for enhancing the effectiveness of written information have been identified as benefits. Limited access to internet for certain people leading to inequality, difficulties in identifying the authors and owners of websites, difficulties in controlling the quality of information, ease of disseminating harmful, incorrect, biased information, limited accountability of providers towards EU citizens have been identified as disadvantages. However, these general considerations do not tell much about the impact of internet-based non-promotional medicine information on consumers' knowledge and choices related to their medication.

There is also a need for evaluation of current practices. Internet-based medicine information has been promoted in several countries. A number of Member States allow for access to online databases on prescription medicines, some sponsored by pharmaceutical companies. For example, the eMC Medicine Guides was developed in the United Kingdom [59] as an online medicines information website for the general public. The Guides contain information about medicines prescribed in the UK, in a language understandable by the general public. Consumers can browse the site also by brand and generic name, as well as by condition name, a feature that could potentially help patients in accessing comparable information concerning their particular condition. Representatives of the pharmaceutical industry promote the site as developed in collaboration with health professionals and patients, accessible from anywhere, and providing customized and comparative information in an interactive way. [60]

There is a need to assess the effectiveness and impact of such internet-based information tools from the perspective of consumers. We should know more about the rela-

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57 B. BRUCE, K. LORIG, D. LAURENT and P. RITTER, "The impact of moderate e-mail discussion group on use of complementary and alternative therapies in subjects with recurrent back pain", *Patient Educ Couns* (58), 2005, pp. 305-311.

58 U. NÄRHI, *Drug information for consumers and patients – A review of the research*, pp. 22-26, *op. cit., supra* note 55.

59 http://medguides.medicines.org.uk; http://www.medicines.org.uk/guides. The eMC Medicine Guides are owned by Datapharm, an independent non-profit company working with the NHS, the pharmaceutical industry and other health care organizations. At the time of writing 38 pharmaceutical companies supported the eMC Medicine Guides.

60 J.M. SHAW *et al.*, "Information for patients on medicines", *op. cit., supra* note 35.

tionship between the provision of information and patients' treatment choices before we take for granted the underlying assumption of the proposed Directive. What is perhaps most unknown is the effect of written medicines information on patients' health outcomes. The ultimate question is whether such information helps patients to become healthier. It is necessary to set the discussion on information provision in the context of impact on patients' health and life quality. Nevertheless, the effect on health outcomes is rarely addressed in the debate; instead, the focus is on the process of information provision.

Conclusion

The underlying assumption of the Commission's proposal is that ensuring access to high quality information will empower consumers to make reasoned treatment choices, which in turn will enhance the rational use of medicines. [61] This might sound like an attractive vision, but the impact of medicines information on patients' treatment choices is not as clear as assumed by the proposal. Ensuring patients' access to medicine information does not guarantee in itself the safe and effective use of medicines. [62] Existing research evidence is not consistent in terms of the effects of written, non-promotional medicine information in enhancing patients' knowledge and understanding of their treatment. [63] There are also significant gaps in the evidence base. Studies published so far have focused mainly on the effectiveness of printed information included in the package leaflets and less on internet-based, non-promotional information. Furthermore, not much is known about the impact of individualized information and the effects of information provision at different phases of treatment (*i.e.* before *vs.* after the prescription decision, etc.). There is a need to increase understanding on the effectiveness of benefit-risk information. Further research is needed on how patients with special needs – including older people, ethnic minorities, and people living with disabilities – use written medicines information.

Given that the impact of information provision on patient health and safety is difficult to evaluate on the basis of existing evidence, it should follow that caution is required. The European Parliament's proposed amendments go some way to reinforcing further the "pull principle" but fundamental issues still remain.

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61 See recital 10 of the Commission proposal.

62 C. BRADLEY, E. HOLME HANSEN and S. KOOIKER, "Patients and their medicines", in E. MOSSIALOS, M. MRAZEK and T. WALLEY (eds.), *Regulating pharmaceuticals in Europe : striving for efficiency, equity and quality*, (Maidenhead, Open University Press, 2004), pp. 159-176, on p. 167.

63 D.K. RAYNOR *et al.*, "A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines", *op. cit., supra* note 28, p. 86.

Finally, the definition of information in the proposed Directive is not yet satisfactory. This means not only that legal uncertainty will prevail in the future, but also that Member States may take different approaches when implementing the Directive, if adopted, into their national legal systems. This would mean that the proposal would not in fact meet its desired objective of achieving greater harmonisation on this matter. Given the continued opposition to any form of information provision by a significant number of Member States it remains to be seen whether the current proposal will fare any better than its predecessors. In the meantime, the difficult task of drawing a fine line between information provision and persuasion or promotion is left to the Union courts. Given that the ECJ has followed its Advocate General's Opinion in the *MSD* v. *Merckle* case, this will go some way to providing a workable set of criteria to distinguish information provision from advertising. Additional legislative safeguards will remain necessary to ensure that the "patient-pull" principle can be fully realised and guaranteed.